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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.     |
|--|-------------|----------------------|---------------------|----------------------|
| 10/560,806   | 05/01/2006  | Erik Andersen        | 4614-0188PUS1       | 6409                 |
| 2292   | 7590        | 02/12/2008           | EXAMINER            |                      |
| BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      |                     | CARPENTER, WILLIAM R |
| 3767   |             | ART UNIT             |                     | PAPER NUMBER         |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/560,806             | ANDERSEN ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | WILLIAM CARPENTER      | 4111                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 May 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/01/2006; 12/15/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/560806, filed on 05/01/2006.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 8 recites the limitation "an axis extending between the first and second common point of contact" [formatting altered for emphasis]. However, there is insufficient antecedent basis for this limitation in the claim, as no "first and second common point of contact" have been previously introduced in Claim 8, or Claims 1 and 4 on which Claim 8 is dependent.
4. Claim 13 recites the limitation "wherein the second surface" [formatting altered for emphasis]. However, there is insufficient antecedent basis for this limitation in the claim, as no "second surface" has been previously introduced in Claim 13, or Claims 1, 11, and 12 on which Claim 13 is dependent.

### ***Claim Rejections - 35 USC § 102***

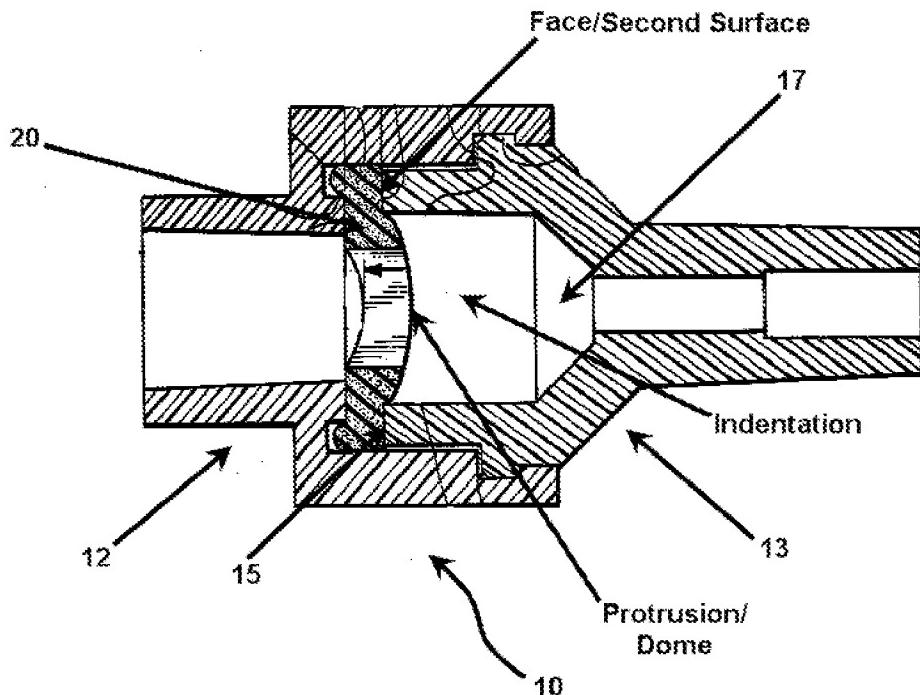
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,143,853 (“Abramson”).

As regards to Claim 1, Abramson discloses a hemostatic valve assembly (10) having a connector comprising a longitudinal main section (13) having a longitudinally extending through-going passage (17). Abramson further discloses the assembly to comprise a valve (13, 12, and 20 in combination) at a proximal end of the connector comprising a closure member (20) having a face (See attached figure) which abuts a proximal end surface (15) of the main section. Abramson further discloses that the closure member comprises a protrusion/dome (See attached figure; Column 2, Lines 40-44) for engaging a corresponding indentation comprising the enlarged interior section (See attached figure) provided in the proximal end surface of the main section.



As regards to Claim 2, Abramson discloses that the closure member is composed of a soft rubber material (Column 2, Lines 40-41). Abramson further discloses that the protrusion/dome is adapted to deform within the indentation when the face and end surface are biased towards one another as to create a liquid tight seal around the periphery of the passage (Column 3, Lines 9-25).

As regards to Claim 3, Abramson discloses the protrusion/dome is integral with the closure member (Figure 2).

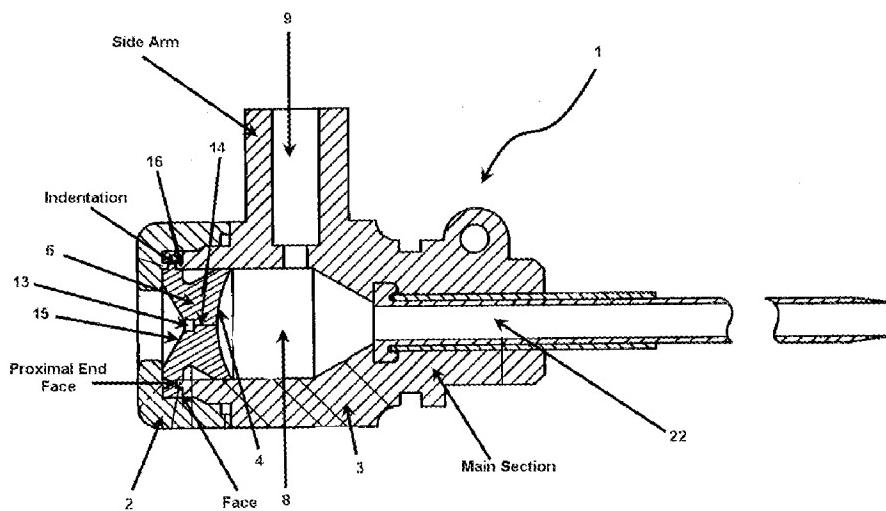
As regards to Claim 11, Abramson discloses the hemostatic valve assembly to comprise a connector (11).

As regards to Claim 12, Abramson discloses that the closure is arranged near a proximal end of the connector (Figure 1).

As regards to Claim 13, Abramson discloses that the second surface of the closure (See attached figure) is oriented to face and abut the proximal end of the connector (15).

7. Claims 1, 2, 4, and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,114,408 ("Fleischhaker et al.").

As regards to Claim 1, Fleischhaker et al. discloses a hemostatic assembly (1) comprising a connector (3) comprising a longitudinally extending main section (See attached figure) having a longitudinally extending through-going passage (8 and 22 in combination) with a valve (2, 3, and 6 in combination) at a proximal end of the connector (See attached figure). Fleischhaker et al. discloses the valve to have a closure comprising a closure member (6) having a face (See attached figure) which abuts a proximal end surface (See attached figure) of the main section. Fleischhaker et al. discloses that the face includes an indentation (See attached figure) which corresponds to a protrusion provided on the proximal end surface (16).



As regards to Claim 2, Fleischhaker et al. discloses that the closure member is composed of a resilient material such as silicone rubber or latex rubber (Column 4, Lines 12-17). While Fleischhaker et al. fails to explicitly disclose that deformation of the closure member occurs at the area of the protrusion and indentation when the face and proximal end surface are biased towards one another in order to form a liquid tight seal near the outer periphery of the passage, it is believed to be inherent that such deformation occurs. The closure member is disclosed as being of a resilient material of a low durometer such that it is flexible, whereas the connector is disclosed as being composed of a considerably harder plastic material such as polycarbonate or polyurethane (Column 4, Lines 1-4). Due to the interlocking nature of the indentation on the closure member and the protrusion on the proximal end face, it is believed to be inherent that some deformation of the low durometer closure member would occur, thereby creating an area of enhanced fluid tight seal as the outer periphery of the passage.

As regards to Claim 4, Fleischhaker et al. discloses that the closure member defines a first and second opposite end surfaces (15 and 4 respectively) and a passage slit (13 and 14) normally closed and extending between the two surfaces (Figure 1). Fleischhaker et al. discloses that the slit is arranged to open by the insertion of a tubular catheter therethrough (Abstract). Fleischhaker et al. discloses that the passage slit comprises a larger pilot opening (13) to accommodate the tubular catheter at the first face.

As regards to Claims 9 and 10, Fleischhaker et al. discloses that a portion of the second face is concave (Figure 1).

As regards to Claim 11, Fleischhaker et al. discloses the hemostatic valve assembly comprises a connector (3).

As regards to Claim 12, Fleischhaker et al. discloses that the valve having the closure member is arranged near the proximal end of the connector (See attached figure).

As regards to Claim 13, Fleischhaker et al. discloses that the second face of the closure is oriented such that it faces the proximal end of the connector (See attached figure).

As regards to Claim 14, Fleischhaker et al. discloses that the connector further comprises a side arm (See attached figure) having a tube (9) disposed therein.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

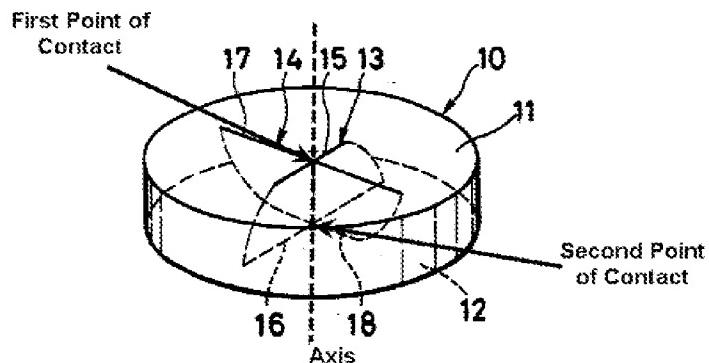
9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. Claims 1-8 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,149,327 ("Oshiyama") in view of US Patent No. 6,569,125 ("Jepson et al.")

As regards to Claims 1, 2, and 3, Oshiyama discloses a hemostatic valve assembly (50) comprising a connector (20) having a longitudinally extending main section (22) having a longitudinally extending through-going passage (See attached figure) with a valve (25) at the proximal end of the main section. Oshiyama discloses this connector to comprise a closure member (10) composed of a resilient material (Column 6, Line 35) having a face (12) which abuts a proximal end surface (See attached figure) of the main section. What Oshiyama fails to explicitly disclose is that the closure member is provided with a protrusion that corresponds with an indentation formed at the end surface. However, Jepson et al. discloses a similar closure member (52) having an integral projection (52a) that corresponds to an indentation (62) at the end surface of the main section (40) of a connector (34). Jepson et al. discloses that the projection of the closure member deforms within the indentation, expanding and filling the indentation (Column 8, Lines 39-45). While Jepson et al. fails to explicitly disclose the benefits of the corresponding projection and indentation, one having ordinary skill in the art would reasonably recognize and appreciate, given the size and location, that the features would provide an increased fluid tight seal around the periphery of the through

going opening and would help to keep the closure member in place to provide sealing contact with the main section. It would have been obvious for one having ordinary skill in the art to similarly apply a projection on the closure member of Oshiyama and a corresponding indentation on the proximal end surface of the main section, as disclosed by Jepson et al., in order to sealingly anchor the closure member to the connector.

As regards to Claim 4, Oshiyama discloses a closure member (10) for a hemostatic valve having a first (11) and second (12) opposite end surfaces. Oshiyama discloses a passage slit (14) being normally closed and extending between the two surfaces. Oshiyama discloses that the passage slit is arranged to open by insertion of a tubular member therethrough (Column 3, Lines 47-50). Oshiyama further discloses that the passage slit has a larger extent at the first surface (17) as compared to the extent at the second surface (18). Oshiyama discloses that such a configuration provides a number of benefits including ease of insertion and preventing leakage (Column 3, Lines 47-63).



As regards to Claim 5, Oshiyama discloses that the closure member comprises a plurality of passage slits (14 and 13) which define a common point of contact (See

attached figure) on the first surface and extend radially outwardly from the point of contact (Figure 1B).

As regards to Claim 6, Oshiyama discloses that the plurality of passage slits form a second point of contact (See attached figure) on the second surface.

As regards to Claim 7, while Oshiyama discloses that the length of the passage slit on the second surface is less than the length of the passage slit on the first surface Oshiyama fails to explicitly disclose that the ratio between the two lengths is less than 1:10. However, as Applicant has failed to explicitly disclose that this particular ratio solves any stated problem or is anything more than one of the numerous configurations for the passage slit one having ordinary skill in the art would have found obvious to use, it would have been a matter of obvious design choice for one having ordinary skill in the art to form the passage slit of the device of Oshiyama such that the egress and the ingress are at a ratio of 1:10.

As regards to Claim 8, Oshiyama discloses that the first end surface and the second end surface define two substantially parallel planes, wherein the axis extending from the first and second common points of contact is substantially parallel to the two planes (See attached figure).

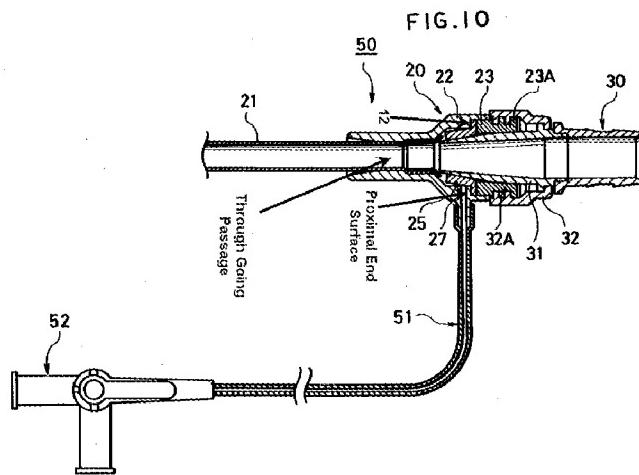
As regards to Claim 11, Oshiyama discloses a connector (20) for a hemostatic valve assembly (50) comprising a valve closure (25).

As regards to Claim 12, Oshiyama discloses that the valve with the closure is arranged near the proximal end of the connector (Figure 10).

As regards to Claim 13, Oshiyama discloses that the second surface of the closure (12) is oriented to face the proximal end surface of the connector (See attached figure).

As regards to Claim 14, Oshiyama discloses a side arm (27) including side arm tubing (51) for the connector (20).

As regards to Claim 15, Oshiyama discloses that the side arm tubing terminates in a stop-cock (52).



11. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,149,327 ("Oshiyama") in view of US Patent No. 6,569,125 ("Jepson et al.") as applied to Claim 4 above, and in further view of US Patent No. 5,114,408 ("Fleischhaker et al.").

As regards to Claims 9 and 10, Oshiyama and Jepson et al. fail to explicitly disclose that the second surface is concave. However, Fleischhaker et al. discloses a similar hemostatic assembly (Figure 1) having a resilient closure member (6) having a concave second surface (4). Fleischhaker et al. discloses that the concave surface

provides the added benefit of maintaining the exit slits (14) in a closed configuration and provides increased sealing (Column 3, Lines 41-47). It would have been obvious for one having ordinary skill in the art to similar concave the second face of the closure member of Oshiyama in order to impart the disclosed benefit of increasing the sealing closure of the exit slits.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-15 of copending Application No. 10/560,827 ("Andersen et al."). Although the scope of the claims is divergent based on a different chain of dependency, the claims are word for word recitations of claims found in the copending application and are therefore drawn to identical inventions.

As regards to Claim 1, Claim 1 is a near identical recitation of Claim 8 of the conflicting application with additional limitations drawn to a "longitudinally extending, through-going passage (110;112) with the valve (128) at a proximal end of the connector". Due to the dependency of Claim 8 of the conflicting application, Claim 8 is a species within the genus that is established by Applicant's Claim 1. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). The additional limitations drawn to the through-going passage and valve can be found in Claims 9 and 1 of the conflicting application respectively, thereby obviating Applicant's Claim 1.

Claims 2 and 3 correspond to Claims 9 and 10 of the conflicting application respectively. Claim 4 -10 correspond to Claims 1-7 of the conflicting application respectively, and Claims 11-15 correspond to Claims 11-15 of the conflicting application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WC  
1/29/2008

/Sam Chuan C. Yao/  
Supervisory Patent Examiner, Art Unit 4111